Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services -Linear Accelerators

Material Related To

Linac Petition-1: Moses Cone Health System

AUG 0/3/2007

MOSES CONE HEALTH SYSTEM

Medical Facilities
Planning Section

Petition for Adjusted Need Determination
Proposed 2008 State Medical Facilities Plan
Addition of Need for a Linear Accelerator with Stereotactic Radiosurgery
Capabilities in Linear Accelerator Service Area 12

Moses Cone Health System (MCHS) submits this petition to the State Health Coordinating Council (SHCC) requesting an adjusted need determination in Linear Accelerator Service Area 12 (Guilford and Rockingham Counties) to add need for one (1) new piece of linear accelerator equipment with stereotactic radiosurgery (SRS) capabilities.

Background

Stereotactic radiosurgery is an advanced form of radiation therapy that combines stereotactic (three dimensional) localization with multiple cross-fired beams from a collimated radiation source from outside the body. This technology allows delivery of a high dose of radiation to a treatment site while keeping the exposure of healthy tissue at a safe level. As a result, larger and more effective doses of radiation can be administered in fewer treatment sessions to a more precise location. SRS can be used to treat tumors that cannot be treated with traditional radiation therapy or surgical techniques because of their location, number, size, shape or proximity to vital tissues or organs, or because of the age or health of the patient.

As will be discussed subsequently, SRS is establishing a unique role as a highly effective therapy for a growing number of tumor sites. Despite this role, the Certificate of Need Section has determined that SRS is a form of linear accelerator equipment, and this petition is submitted in the context of this determination.

¹ Image-Guided Radiosurgery in the Treatment of Spinal Metastases, Murphy, at al. Neurosurgical Focus. 2001 Dec 15; 11(6):e6.

Rationale for Adjusted Need Request

An adjusted need determination for an SRS-capable linear accelerator is essential to providing state-of-the-art care to the patient population of Linear Accelerator Service Area 12 that currently lacks access to this technology within the defined service area, has a sufficient patient population base to support SRS (greater than 500,000 residents), yet cannot currently acquire SRS technology without negatively affecting existing capacity for established radiation therapy services. The following discussion presents the rationale for approving the requested adjusted need determination.

Clinical Applications

Stereotactic radiosurgery clinical applications are both proven and expanding. SRS technology has been used for more than 30 years, and over 100,000 patients have been treated worldwide. In its earliest form, SRS was used to treat only intracranial (head and neck) tumors or lesions via a Gamma Knife. This system, however, utilizes a rigid metal frame that is fixed to the patient's skull, immobilizing the head so that damage to the healthy tissue surrounding the tumor is minimized when the radiation is delivered. Advancements in technology that can provide SRS via a linear accelerator now enable the delivery of high doses of radiation to intracranial tumors without a metal head frame or to extracranial tumors, such as spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion.

Linear accelerators with SRS capabilities are manufactured by Elekta, Novalis, Accuray, Tomotherapy and Varian. This petition does not attempt to highlight one manufacturer over another; rather, this petition seeks to add SRS capabilities to the complement of radiation therapy services provided to residents of Linear Accelerator Service Area 12 without diminishing existing capabilities for traditional radiation therapy.

SRS is one of the fastest-growing areas of oncologic radiation therapy. Sg2, a health care intelligence firm, forecasts that SRS for the treatment of intracranial cancer will grow 108% over the next ten (10) years and SRS for extracranial cancer treatment will grow an astonishing 255% over the next ten (10) years. Intracranial utilization of SRS will increase as the technology is used for patients with multiple or recurrent brain lesions once thought to be untreatable, as clinical efficacy improves for non-cancer indications, such as functional disorders and acoustic neuromas, as incidence of brain metastases increases due to improved survival rates for other primary cancers, and as public awareness and interest in receiving state-of-the-art care increases. Additional factors affecting an increase in utilization of SRS for extracranial applications include growing clinical efficacy of extracranial applications and non-cancer indications, such as benign tumors, increased cancer incidence as a result of an aging population and treatment advances that extend patient longevity, and increasing public awareness and interest in receiving state-of-the-art care.²

Physician support for the addition of SRS equipment in Service Area 12 is well established; this support underscores the need for the proposed adjusted need determination. Because SRS is capable of treating both intra- and extracranial tumors, neurosurgeons, oncologists, and radiation oncologists all support the need for availability of SRS for a variety of clinical applications, as evidenced by support letters presented in Exhibit I.

Geographic Access

Current access to intra and extracranial SRS technology for patients living in Service Area 12 is limited. Table 1 lists the current providers of stereotactic radiosurgery in North Carolina and the associated SRS technology.

² Sg2 Clinical Intelligence. Stereotactic Radiosurgery: Strategies for Success. 2006.

Table 1
Current North Carolina SRS Providers

Hospital/Facility and City	SRS-Capable Equipment	Intra/Extracranial Capability	Number of Procedures FY 2006
NC Baptist Hospital, Winston-Salem	Gamma Knife, SRS Linac	Intracranial Only. Intra and Extracranial	Gamma knife - 285 SRS - 24
Carolinas Medical Center - Northeast. Concord	Cyberknife	Intra and Extracranial	Not operational in FY 2006
Carolinas Medical Center, Charlotte	Novalis SRS Linac	Intra and Extracranial	95
UNC Hospitals, Chapel Hill	SRS Linac	Intra and Extracranial	62
Duke University Hospital, Durham	Varian SRS Linac and Xknife	Intra and Extracranial	115
Memorial Mission Hospital, Asheville	Cyberknife	Intra and Extracranial	272
Pitt County Memorial Hospital/Brody School of Medicine, Greenville	Gamma Knife and CON application pending for Cyberknife to replace existing SRS-capable unit	Intracranial only for Gamma Knife, Intra and extracranial for SRS Linac	Gamma Knife – 105 SRS – 0
Carolina Radiation Medicine, Greenville	Varian SRS Linac	Intra and extracranial	24

Source: Proposed 2008 State Medical Facilities Plan, facility websites, and "Robot Performs Cancer Surgery", News and Observer, July 2, 2007, newsobserver.com.

Exhibit II presents a map depicting the location of these established SRS providers in North Carolina. Several regions within the state experience excessive distances and travel times for stereotactic radiosurgery, often leading to greater hardships on patients and their families and/or the limitation of referral opportunities. This situation is particularly true in Service Area 12, where the size of the resident population warrants more immediate access to SRS technology.

Additionally, existing or planned stereotactic radiosurgery programs have been developed to serve their established service area populations only; they do not include service to other areas with a sufficient population experiencing high utilization of one or more established linear accelerator providers, i.e. Service

Area 12. Hence, these programs are not positioned to meet the significant demand for SRS treatments from the Service Area 12 resident population.

Current SMFP Linear Accelerator Need Methodology

The current methodology used in the SMFP to determine need for additional linear accelerators does not account for the unique technological aspects of SRS. Although the technology is delivered via an SRS-capable linear accelerator, radiosurgery is a longer procedure than traditional radiation therapy. Average treatment time is 140 minutes in duration depending on tumor location and complexity of treatment plan. The treatment plan will require from one to five fractions or treatments to complete the plan. Therefore, the traditional criterion for evaluating radiation therapy capacity, 6,500 Equivalent Simple Treatment Visits (ESTVs) per linear accelerator annually, does not accurately reflect the utilization patterns for radiosurgery. The capacity for stereotactic radiosurgery equipment is approximately 350 patients per year at an average of three (3) treatments per patient and weight of 3.00 or 3,150 ESTVs per year³. By comparison, traditional radiation therapy protocols provide thirty (30) or more treatments per patient at approximately fifteen (15) minutes per treatment.

Additionally, the current SMFP linear accelerator need methodology generates need on a service area-wide basis rather than a facility-specific basis. Therefore, a facility that is highly utilized and at or near capacity, yet is part of a service area with other less-utilized facilities, operates at a significant disadvantage. Because the need methodology does not account for individual facility utilization levels, the well-utilized facility is thwarted from obtaining new equipment to meet established trends in patient demand.

The current linear accelerator need methodology also requires a Service Area to meet two (2) of three (3) criteria in order to generate a need. In addition to the utilization standard, one of the criterion states that a Service Area should have a

³ Sg2 phone conversation and Proposed 2008 State Medical Facilities Plan Table 9F.

population greater than 120,000 per linear accelerator in order to generate need. With a total 2007 population of 547,202 in Service Area 12 and seven (7) existing linear accelerators, population per linear accelerator is 78,172. With projected annual population growth of 1.1% for the Service Area, this criterion will not be met until 2049, well beyond the point at which utilization exceeds capacity. Another criterion can be met when 45% or more of patients come from outside the service area. As an urban area without an academic medical center, it is unlikely that Service Area 12, in particular Moses Cone Health System will trigger this criterion. Therefore, even when utilization of existing linear accelerators reaches capacity, it is unlikely that Service Area 12 will meet either of the other two (2) criterion. It is important to note that MCHS was at 105.0% of capacity for FY 2006 and has been over 96.0% of capacity for the last five (5) years. Therefore, Service Area 12 will need its existing linear accelerators to meet demand for traditional radiation therapy, leaving no excess capacity available to meet demand for SRS.

SRS volume forecasts indicate a sufficient number of patients to justify the use of this equipment to serve the Area 12 resident population. MCHS employed a model developed by Accelitech, a company specializing in business planning and feasibility studies, to project potential SRS patient volume. Using cancer incidence rates, the assumption that 60% of all cancer patients will receive some form of radiation therapy, and the percentage of patients receiving treatment with other forms of radiation, including SRS, MCHS projects that the total number of patients in Area 12 who would be clinically appropriate to receive SRS treatments is 656 in 2007 and 695 in 2012, five years later. Table 2 provides potential SRS volumes for Area 12.

<u>Table 2</u>
<u>Estimated and Projected Area 12 SRS Patients</u>

	2007	2012	# Change	% Change
Estimated Total Potential Patient Volume	656	695	39	5.95%

Source: Accelitech Model

Moses Cone Health System

As previously stated, the capacity of SRS equipment is approximately 350 patients, or approximately half of the projected demand for SRS patient volume in Service Area 12. This capacity estimate is based on a model developed by Sg2 which employs the following assumptions: average treatment time of 140 minutes, three fractions of treatment per patient, operating 270 days per year, and10 hours per day. MCHS anticipates serving a significant portion of the projected Area 12 demand should it receive CON approval for an SRS capable linear accelerator, while a portion of the patients who live in the service area will receive treatment at other facilities that offer SRS technology. Of particular note, this projected Service Area 12 demand for SRS services matched with the capacity of SRS equipment underscores the vital need for SRS technology in this service area.

A service area population of 500,000 or more supports the need for SRS equipment that has a capacity of 350 patients annually. Table 3 presents a potential SRS patient volume scenario demonstrating that 295 patients in 2007 and 313 patients in 2012 could receive treatment at a CON approved MCHS facility. The projected 2012 patient volume is approximately 90% of capacity, thereby allowing for anticipated growth in the number of patients receiving treatment at such an SRS program.

Table 3 Service Area 12 SRS Patient Volume Scenario - 2007 and 2012

	2007	2012
Service Area 12 Population	547,202 ⁽¹⁾	576,892 ⁽⁴⁾
Estimated SRS Patient Volumes	656 ⁽²⁾	695 ⁽²⁾
MCHS Market Share	45% ⁽³⁾	45% ⁽³⁾
MCHS SRS Patient Volumes	295	313
MCHS SRS Capacity Utilization ⁽⁵⁾	84.3%	89.4%

⁽¹⁾ Proposed 2008 State Medical Facilities Plan, Page 113.

Source: As noted above.

Moses Cone Health System.

Alternatives Considered

Moses Cone Health System considered a number of alternatives to submitting this petition to adjust the need determination in the 2008 SMFP including maintaining the status quo, replacing an existing MCHS linear accelerator, and developing a relationship with another area radiation oncology provider. None of these options was deemed superior to submitting a petition for an adjusted need determination and, therefore, all were rejected.

Maintain the Status Quo

One alternative considered was to maintain the status quo and not pursue the acquisition of stereotactic radiosurgery (SRS) technology. This option would have the obvious advantage of eliminating the necessary capital cost. However,

⁽²⁾ See Table 2.

⁽³⁾ Market share estimated based on current MCHS Medical Oncology market share percent.
(4) North Carolina Data Center.

⁽⁵⁾ Based on annual capacity of 350 patients.

this option would not allow patients in Service Area 12 to benefit from convenient access to SRS technology. Currently the closest provider of SRS treatment is located at NC Baptist Hospital in Winston-Salem, NC, which is approximately twenty-eight (28) miles from Greensboro, forty-three (43) miles from Reidsville, and almost fifty (50) miles from Eden, three of the major cities in Area 12. This distance may impede SRS referrals for many Area 12 residents. Exhibit III demonstrates excessive travel times and distances from established and CON pending SRS facilities. In addition, since SRS patients often have to return several times for treatment, a shorter travel distance will be more convenient for patients and their families.

The technology requested in this petition represents state-of-the-art technology. It can be used to treat intra and extracranial tumors, thus serving a large and expanding pool of potential patients. Moreover, SRS technology provides improved accuracy in targeting the tumor which greatly reduces damage to the surrounding, healthy tissue.

Replace an Existing MCHS Linear Accelerator

Replacement of an existing MCHS linear accelerator with SRS technology was also considered. Due to the high utilization levels of MCHS's four (4) existing linear accelerators, replacing an existing linear accelerator with SRS technology would significantly reduce capacity for serving radiation oncology patients. Table 4 lists the utilization of MCHS's existing linear accelerators.

Table 4

<u>Moses Cone Health System Linear Accelerator Volumes FY 2002 – 2006</u>

						Change !	FY 02-06
- -	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	#	%
ESTVs	26,883	28,947	26,097	26,824	28,362	1,480	5.5%
# of Linear Accelerators	4	4	4	4	4	0	0.0%
ESTVs/Linear Accelerator	6,721	7,237	6,524	6,706	7,091	370	5.5%
% Utilization (1)	99.6%	107.2%	96.7%	99.3%	105.0%	5.5%	5.5%

Note: ESTV = Equivalent Single Treatment Visit

Source: Annual Hospital License Renewal Applications

MCHS has been above 96% capacity since FY 2002 and for FY 2006 was operating at 105% of capacity.

As previously described, SRS patients are best served through equipment dedicated to providing SRS services. MCHS's historically high utilization of its existing linear accelerator capacity simply does not permit the replacement of one of these machines with a SRS capable linear accelerator. Under this scenario, both radiation oncology and SRS patients would suffer from unacceptable wait times for treatment.

Develop a Relationship with Another Area Radiation Oncology Provider

Moses Cone Health System also considered developing a relationship with another area radiation oncology provider. Table 5 lists close hospitals that provide radiation oncology services, the number of unduplicated patients treated, and the number of ESTV procedures performed in FY 2006.

⁽¹⁾ Based on the annual capacity of 6.750 ESTV procedures, as set in the State Medical Facilities Plan.

Table 5
Selected North Carolina Hospitals Providing Radiation Oncology Services

	FY 2	006
Radiation Oncology Provider	Number of Unduplicated Patients	Number of ESTV Procedures
Moses Cone Health System	1.080	28,362
High Point Regional Health System	389 (*)	9,623(1)
Morehead Memorial Hospital	217	5,972
Alamance Regional Medical Center	305	7,991

From 2006 Hospital License Renewal Application, p. 14 and 15 due to an apparent inconsistency in the 2007 Application as compared to other years, for the number of unduplicated patients.

Source: 2007 Hospital License Renewal Applications, p. 14 and 15.

Currently within Area 12, there are two other radiation oncology providers, High Point Regional Health System and Morehead Memorial Hospital. Neither of these programs have the scope and comprehensiveness of services necessary to develop a SRS program. Alamance Regional Medical Center, while outside Service Area 12 but located close to Moses Cone Health System, also lacks the capacity to serve additional SRS patients. The aforementioned hospitals are small to medium sized community hospitals and do not have the size, technological infrastructure, and breadth of physician specialties on staff to be a viable partner with MCHS to develop a SRS program. Supporting this conclusion, please see Exhibit IV for letters from High Point Regional Health System and Morehead Memorial Hospital supporting this petition.

The closest SRS provider to Area 12 is NC Baptist Hospital, located in Winston-Salem. UNC Hospital, the next closest facility that provides SRS treatments is fifty-six (56) miles from Greensboro, a distance which would cause referral and travel difficulties for patients in need of treatment.

After thoroughly examining these three alternatives, MCHS decided that submitting this petition was the best option to provide Area 12 residents with state-of-the-art technology within close proximity to their homes and without

reducing capacity for patients in need of highly utilized, traditional radiation treatments.

No Unnecessary Duplication of Health Care Resources

The addition of a need determination for a linear accelerator with SRS capability will not result in unnecessary duplication of health care resources for the following reasons:

- Linear Accelerator Service Area 12 currently contains no SRS capable
 equipment. MCHS and its physicians are uniquely qualified to offer this
 service by expanding its well-established, well-utilized radiation oncology
 program.
- 2. MCHS's existing linear accelerators are operating above 100% capacity (6,750 ESTVs/linear accelerator) as noted in Table 4.
- Patient volumes for SRS, both intra and extracranial, will grow substantially
 over the coming years due to the clinical applications of the technology and
 the expected growth in incidence of cancers that may benefit from treatment
 using SRS.
- 4. The current linear accelerator need methodology is service area based. Hence, it penalizes those providers who operate at high utilization while other service area providers do not. This situation limits a well-utilized program from upgrading existing equipment without incurring negative consequences for existing patients and clinical needs.

Adjusted Need Determination Request

Moses Cone Health System respectfully requests that the 2008 State Medical Facilities Plan include an adjusted need determination for a linear accelerator providing stereotactic radiosurgery capabilities in Service Area 12 based on the following criteria:

1. The Service Area 12 2007 resident population exceeds 500,000, a size sufficient to support a stereotactic radiosurgery program.

- As documented in the Proposed 2008 State Medical Facilities Plan, Moses Cone Health System provided linear accelerator services above the performance threshold of 6,750 ESTVs per linear accelerator for FY 2006.
- No stereotactic radiosurgery providers exist in Service Area 12.
 Moreover, the potential for establishing the need for a linear accelerator with SRS capability, absent an adjusted need determination, will not occur for many years to come.

EXHIBIT I



August 3, 2007

501 North Elani Aceiue Greensbero, NC, 27403-1199

Writer's Direct Number

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown:

I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

Service area 12 has a large population and one linear accelerator provider, MCHS, which is operating above capacity. If MCHS were to replace an existing linear accelerator with SRS equipment, it would significantly reduce capacity, as throughput on SRS machines is much lower than on traditional linear accelerators. This would cause a significant barrier to access for patients in need of traditional radiation treatments as well as SRS, a new, cutting-edge technology. Therefore, we believe adding need for a linear accelerator with SRS technology is the only way to ensure high quality, accessible care to the residents of service area 12.

SRS is one of the fastest-growing areas of oncologic radiation therapy. As Radiation Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. SRS provided via a linear accelerator now enables the delivery of high doses of radiation to intracranial tumors without a metal head frame and to extracranial tumors such as the spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion. Intercranial utilization of SRS is projected to increase based on several factors: the technology can be used for patients with multiple or recurrent brain lesions once thought to be untreatable; clinical efficacy will continue to improve for non-cancer indications, such as functional disorders and acoustic neuromas; treatment of brain metastases will increase due to improved survival rates for other primary cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely

Pohert Murrole M.D.



August 3, 2007

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James Kinard, M.D.



August 3, 2007

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As Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. We currently refer patients each year to SRS providers outside of area 12. We are acutely aware of the hardship this causes our patients who must make multiple trips to receive treatment.

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Sincerely,

John Feldmann, M.D.



August 3, 2007

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I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

Service area 12 has a large population and one linear accelerator provider, MCHS, which is operating above capacity. If MCHS were to replace an existing linear accelerator with SRS equipment, it would significantly reduce capacity, as throughput on SRS machines is much lower than on traditional linear accelerators. This would cause a significant barrier to access for patients in need of traditional radiation oncology as well as SRS, a new, cutting-edge technology. Therefore, we believe adding need for a linear accelerator with SRS technology is the only way to ensure high quality, accessible care to the residents of service area 12.

SRS is one of the fastest-growing areas of oncologic radiation therapy. As Neurosurgeons, we are acutely aware of the increasing utilization of SRS therapies in treating intracranial spinal tumors. SRS provided via a linear accelerator now enables the delivery of high doses of radiation to intracranial tumors without a metal head frame and to extracranial tumors such as the spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion. Intercranial utilization of SRS is projected to increase based on several factors: the technology can be used for patients with multiple or recurrent brain lesions once thought to be untreatable; clinical efficacy will continue to improve for non-cancer indications, such as functional disorders and acoustic neuromas; treatment of brain metastases will

increase due to improved survival rates for other primary cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely.

Henry Elsner, MD

Mark Roy, MN

Kyle Cabbell, MD

Robert Nudelman, MD

Jeffrey Jonkins, MD

James Hirsch, MD

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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Sincerely,

Randy O. Kritzer, M. D.

Neurosurgeon

Carolina Neurosurgery, P.A. 301 E. Wendover Ave, Suite 211

Greensboro, NC 27401

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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Sincerely,

David Jones, M. D.

Neurosurgeon

Carolina Neurosurgery, P.A. 301 E. Wendover Ave, Suite 211

Greensboro, NC 27401

EXHIBIT II

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Existing SRS Locations in North Carolina



EXHIBIT III

Exhibit III
Distance and Travel Times to Existing SRS Facilities

	Greensboro	High Point	Reidsville	Eden (Rockingham
	(Guilford Co.)	(Guilford Co.)	(Rockingham Co.)	Co.)
Carolinas Mad Contar Charlotte	94.5 miles	84.2 miles	118.5 miles	131.0 miles
	1 hour, 41 minutes	1 hour, 27 minutes	2 hours, 6 minutes	2 hours, 24 minutes
Product tacadtack ONO	69.7 miles	59.3 miles	93.6 miles	106.1 miles
	1 hour, 15 minutes	1 hour	1 hour, 40 minutes	1 hour, 58 minutes
Carolina Radiation Medicine,	162.3 miles	176.2 miles	182.6 miles	202.2 miles
Greenville 2 t	2 hours, 53 minutes	3 hours, 3 minutes	3 hours, 15 minutes	3 hours, 48 minutes
Duke the vereity Hoenitel Durham	52.1 miles	65.9 miles	64.8 miles	77.3 miles
Dane Olliversity (10spital, Dalliall)	58 minutes	1 hour, 9 minutes	1 hour, 19 minutes	1 hour, 38 minutes
Memorial Mission Hospital,	169.8 miles	161.4 miles	194.3 miles	192.1 miles
Ashevilie 2 h	2 hours, 47 minutes	2 hours, 39 minutes	3 hours, 16 minutes	3 hours, 27 minutes
NC Bantiet Hoenital Wineton Calom	27.9 mites	22.0 miles	43.3 miles	47.9 miles
No Daptier (103piter), milliotoli Saletti	35 minutes	29 minutes	55 minutes	1 hour, 11 minutes
Pitt County/Brody School,	161.0 miles	174.8 miles	181.2 miles	200.9 miles
Greenville	2 hours, 51 minutes	3 hours, 2 minutes	3 hours, 13 minutes	3 hours, 46 minutes
IINC Chapel Hill Chapel Hill	56.0 miles	69.9 miles	68.8 miles	81.2 miles
	1 hour, 3 minutes	1 hour, 14 minutes	1 hour, 24 minutes	1 hour, 42 minutes

Source: Microsoft MapPoint 2004

EXHIBIT IV



Jeffrey S. Miller President

August 2, 2007

Ms. Elizabeth Brown, Chief Medical Facilities Planning Section The Division of Health Service Regulation North Carolina Department of Health and Human Services 2714 Mail Service Center Raleigh, NC 27699-2714

Dear Ms. Brown:

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotactic radiosurgery capabilities to Service Area 12. High Point Regional Health System is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotactic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Jeffrey S. Miller

President



August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown.

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotatic radiosurgery capabilities to Service Area 12. Morehead Memorial Hospital is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. This new linear accelerator will not take volume from any of the existing facilities as it will be a dedicated unit only used for stereotatic radiosurgery, a service currently not available in Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotatic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Sincerely,

Robert A. Enders, Jr.

Robert A. Ender h

President

117 East Kings Highway Eden, North Carolina 27288-5201 TEL 336.623.9711 www.morehead.org

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services -Linear Accelerators

Comments Related To

Linac Petition-1: Moses Cone Health System

Comment -1 Jim Whiting Comment -2 Dr. Henry A. Pool

Graphsbor PH 1-20-07 Lin AC

Proposed 2008 State Medical Facilities Plan Public Hearing July 20, 2007

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Moses Cone Health System

Remarks Made Supporting an Adjusted

Need Determination for a Linear Accelerator

with Stereotactic Radiosurgery Capability

in Service Area 12

Medical Facilities Planning Section

Good Afternoon. My name is Jim Whiting, and I am the Vice President for Moses Cone Health System's Regional Cancer Center. My remarks today address the need to provide immediate access to Stereotactic Radiosurgery (SRS) technology for the residents of linear accelerator Service Area 12 comprising Guilford and Rockingham counties. Serving this unmet need is essential to insuring a full array of state-of-the-art therapy services to this region's population, which currently totals over 541,000 residents. However, existing State Medical Facilities Plan need methodologies effectively block the addition of SRS technology in our area. As a result, Moses Cone Health System intends to submit a petition for an adjusted need determination for the addition of a linear accelerator with SRS capabilities.

Our petition will be based on the following major points:

- Stereotactic radiosurgery is both a proven and expanding modality for the treatment of both intra and extra cranial tumors.
- Physicians directly involved with the care of patients who could benefit most from SRS, most notably neurosurgeons, thoracic surgeons and radiation oncologists on staff at Moses Cone Health System, strongly support the addition of this technology.
- 3. Current geographic access to SRS services for Area 12 residents is limited.

- No SRS providers exist in Guilford or Rockingham counties.
- While other service areas provide SRS, travel to these programs imposes a burden on Area 12 patients and families.
- The Service Area 12 resident population is of a sufficient size, greater than 500,000, to warrant the development of a SRS program.
- 5. The current SMFP need methodology for linear accelerators is area and not provider specific. As a result, lower utilized facilities in a given service area can prevent the determination of an identified need despite one or more providers operating at or above capacity.

This situation is currently found in Area 12, where MCHS operates at over 100% capacity on its four (4) linear accelerators, while Morehead Memorial Hospital and High Point Regional Health System operate at 79.9% and 69.2%, respectively.

- 6. MCHS has considered a number of alternatives to requesting an adjusted need determination:
 - The status quo fails to meet the unmet need for SRS services.
 - Replacing an existing linear accelerator at MCHS with a stereotactic radiosurgery machine significantly reduces MCHS radiation oncology capacity. SRS patients require longer treatment times; a machine dedicated to SRS will best meet the clinical needs of these patients.
- 7. No unnecessary duplication of services will result from the approval of this adjusted need determination. Indeed, our petition is based on the current lack of SRS capabilities in Area 12.

Our petition will expand on each of these major points. I am hopeful that the Medical Facilities Planning Section staff and the State Health Coordinating Council will look favorably at our request.

Thank you.

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AUG 03 2007

August 3, 2007

Medical Facilities
Planning Section

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
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